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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/257,272	02/25/1999	JING-SHAN HU	PF112P2D2	1980

22195 7590 11/23/2001

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

LANDSMAN, ROBERT

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/23/2001

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/257,272

Applicant(s)

HU ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-400 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-400 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Formal Matters

- A. Applicants' response to Paper No. 8, filed 9/12/01, has been entered into the record.
- B. Claims 22-32 have been cancelled and new claims 33-400 have been added. Therefore, claims 33-400 are pending in this application.
- C. The IDS, filed 3/23/01, has been entered into the record.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Information Disclosure Statement

- A. The Statutory Declarations on the IDS of Paper No. 6 have been considered, but these entries are not proper subject matter for an IDNS and will, therefore, not be printed on an IDS.

Withdrawn Claim Rejections

1. Claim Rejections - 35 USC § 112, second paragraph

- A. The rejection of claims 33-400 under 35 USC 112, second paragraph, regarding Applicants reciting "an unreasonable number of claims" has been withdrawn since searching these claims would not be an undue burden on the Examiner.
- B. The rejection of claims 33-400 under 35 USC 112, second paragraph, regarding the present application repeating claims which have been patented in U.S. Patent No. 5,932,540 and U.S. Application Serial No. 09/219,442 has been withdrawn since the present application recites the limitation "90% identical" wherein U.S. Patent No. 5,932,540 and U.S. Application Serial No. 09/219,442 do not.

New Claim Rejections

1. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 97-192, 305-336, 342-346, 352-356 and 379-400 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The deposit of the biological material is considered necessary for the enablement of the current invention (see MPEP Chapter 2400 and 37 C.F.R. §§ 1.801-1.809). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. As Applicants have not provided the deposit number for plasmids ATCC 75698 and 97149, the specification is not fully compliant with all of the provisions for maintenance and availability of the deposited material. If a deposit is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g. see 961 OG 21, 1977), and Applicants, their assignee or their agent needs to provide a declaration containing the following:

a) a statement all restrictions on the availability to the public of the deposited material so deposited will be irrevocably removed upon the granting of a patent.

b) A statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.

c) A statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

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d) A statement by declarant that all statements are true and that all statements made on information and belief are believed to be true; and further that these statements were made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

B. Claims 33, 34, 49, 50, 65, 66, 81, 82, 97, 98, 113, 114, 129, 130, 145, 146, 161, 162, 177, 178, 193, 194, 209, 210, 225, 226, 241, 242, 257, 258, 273, 274, 289, 290, 305, 306, 321, 322, 337, 338, 342, 343, 347, 348, 352, 353, 357, 358, 368, 369, 379, 380, 390 and 391 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2 and 4, does not reasonably provide enablement for proteins which are “**at least 90% identical**” to SEQ ID NO:2 or 4. Applicants would be enabled for ATCC Deposit Nos. 75698 and 97149 if and when they meet the Deposit Requirements as stated in the above rejection under 35 USC 112, first paragraph, but would not be enabled for proteins which are “**at least 90% identical**” to the proteins encoded for by these vectors. Furthermore, Applicants are not, or would not be, enabled for “**fragments**” of less than the full-length of the proteins encoded for by SEQ ID NO:2, 4 or ATCC Nos. 75698 and 97149, including residues 1-396, or smaller, or fragments comprising “**at least 30 contiguous amino acids**” of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is extensive with regard to claiming all proteins which are “**at least 90%**” identical to, or “**fragments**” of SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149. of SEQ

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ID NO:2. Proteins which are **“at least 90%”** identical to the proteins of SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149 would have one or more amino acid substitutions, deletions, insertions and/or additions to the proteins encoded for by SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149.

Applicants provide no guidance or working examples of nucleic acid molecules which hybridize to the complement of SEQ ID NO:1, which encode proteins which are **“at least 90%”** identical to, or comprise amino acids **1-396, or fewer**, or to fragments comprising **“at least 30 contiguous amino acids”** of SEQ ID NO:2. Applicants do recite in the claims that the protein fragments which are less than the full-length proteins must have specific functions. However, Applicants provide no guidance or working examples of what amino acids can be altered (added, substituted, or deleted) in order to maintain the desired activity of these fragments. Furthermore, it is not predictable to one of ordinary skill in the art what residues can be altered while still providing the desired peptide function.

In summary, the breadth of the claims is extensive with regard to Applicants claiming all proteins which are **“at least 90%”** identical to SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149. In addition, Applicants provide no guidance or working examples of how to use said peptides, such as peptides of amino acids 1-396, or fewer of SEQ ID NO:2, or of at least 30 contiguous amino acids of SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149 which retain the claimed biological function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a peptide smaller than the full-length protein which is able to retain biological activity, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

Claims 35-48, 51-64, 67-80, 83-96, 99-112, 115-128, 131-144, 147-160, 163-176, 179-192, 195-208, 211-224, 227-240, 243-256, 259-272, 275-288, 291-304, 307-320, 323-336, 339-341, 344-346, 349-351, 354-356, 359-367, 370-378, 381-389 and 392-400 are rejected since they depend from rejected base claims.

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2. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 33, 34, 49, 50, 65, 66, 81, 82, 97, 98, 113, 114, 129, 130, 145, 146, 161, 162, 177, 178, 193, 194, 209, 210, 225, 226, 241, 242, 257, 258, 273, 274, 289, 290, 305, 306, 321, 322, 337, 338, 342, 343, 347, 348, 352, 353, 357, 358, 368, 369, 379, 380, 390 and 391 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Proteins which are “**at least 90% identical**” to the proteins of SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149 would encode for a protein with one or more amino acid substitutions, deletions, insertions and/or additions to the protein encoded for by SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149. Furthermore, Applicants have not provided adequate written description of “**fragments**” of less than the full-length of the proteins encoded for by SEQ ID NO:2, 4 or ATCC Nos. 75698 and 97149, including residues 1-396, or smaller, or fragments comprising “**at least 30 contiguous amino acids**” of SEQ ID NO:2.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:2, 4, or to ATCC No. 75698

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and 97149, alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made. Claims 35-48, 51-64, 67-80, 83-96, 99-112, 115-128, 131-144, 147-160, 163-176, 179-192, 195-208, 211-224, 227-240, 243-256, 259-272, 275-288, 291-304, 307-320, 323-336, 339-341, 344-346, 349-351, 354-356, 359-367, 370-378, 381-389 and 392-400 are rejected since they depend from rejected base claims.

3. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 33, 34, 49, 50, 65, 66, 81, 82, 97, 98, 113, 114, 129, 130, 145, 146, 161, 162, 177, 178, 193, 194, 209, 210, 225, 226, 241, 242, 257, 258, 273, 274, 289, 290, 305, 306, 321, 322, 337, 338, 342, 343, 347, 348, 352, 353, 357, 358, 368, 369, 379, 380, 390 and 391 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. First, the wording of these claims is confusing. The claims read as if the isolated protein is a fusion protein, since they recite "first protein" and "second protein." Second, some of these claims recite a "first protein" without reciting a "second protein." The claims would be clearer if they were amended to recite, for example, "An isolated protein which is at least 90% identical to the protein of SEQ ID NO:2," or "An isolated protein which is at least 90% identical to the protein encoded for by the cDNA contained in ATCC Deposit No. 75698."

Claims 35-48, 51-64, 67-80, 83-96, 99-112, 115-128, 131-144, 147-160, 163-176, 179-192, 195-208, 211-224, 227-240, 243-256, 259-272, 275-288, 291-304, 307-320, 323-336, 339-341, 344-346, 349-351, 354-356, 359-367, 370-378, 381-389 and 392-400 are rejected since they depend from rejected base claims.

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B. Claims 33-160 are confusing. These claims recite both the "mature" and "preprotein" forms of the claimed proteins. It is not clear what constitutes, or differentiates, these forms. The ATCC Deposits each comprise only one cDNA and it is not clear whether this cDNA encodes the entire open reading frame of the proteins, or comprises other nucleic acids as well.

Closest Prior Art

The closest prior art is Paulsson G. et al. (ATCC Accession No. S08167) who teaches an amino acid sequence which is 11% identical to SEQ ID NO:2 and 12.9% identical to SEQ ID NO:4.

Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 19, 2001


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SEQ ID NO:2

S08167

Balbani ring 3 protein - midge (Chironomus tentans)

C;Species: Chironomus tentans

C;Date: 30-Sep-1991 #sequence_revision 30-Sep-1991 #text_change 21-Jul-2000

C;Accession: S08167

R;Paulsson, G.; Lendahl, U.; Galli, J.; Ericsson, C.; Wieslander, L.

J. Mol. Biol. 211, 331-349, 1990

A;Title: The balbani ring 3 gene in Chironomus tentans has a diverged repetitive structure split by many introns.

A;Reference number: S08167; MUID:90172404

A;Accession: S08167

A;Status: not compared with conceptual translation

A;Molecule type: DNA

A;Residues: 1-1700 <PAU>

A;Cross-references: GB:X52263; NID:g7057; PIDN:CAA36506.1; PID:g7058

C;Genetics:

A;Gene: BR3

A;Map position: 4

C;Superfamily: unassigned Balbani ring proteins

Query Match 11.0%; Score 257; DB 2; Length 1700;
Best Local Similarity 22.8%; Pred. No. 4.9e-11;
Matches 89; Conservative 47; Mismatches 145; Indels 110; Gaps 18;

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Qy      79 KMYKCQLRK----GGWQHNREQANLNSRTEETIKFAAAHYNTEILKSIDNEWKRTQCMR 134
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Db      727 KTCKCKCEKEMPTGGCENNKKWC-----DETCDCVCPQKNTCIAPKV---WDAKTCS-- 775

Qy      135 EVCIDVGKEFGVATNTFFKPPCVSVYRCGG-----CCNSEGLQCMNTSTSYLSKTLF 186
      ||  ||: :|  || : :  || : :  || : :
Db      776 --CI-----CVNPPKCNSPQVLKDTCCCGCQNVKSKAPQKFI-ENIC 815

Qy      187 EITVPLSQGPKPVTISFANHTSCRCMSKLDV-----YRQVHSIIRRSLPATLPQCQA 238
      : | : | : | | : : : : | : | : | |
Db      816 DCACPNKKQCKAPLVWSDEFDCVCPCNSASMKTCLSPKEWNKVTCTCDCNPPK--PDC-- 871

Qy      239 ANKTCPTNYMWNHICRC---LAQEDFMFSSDAGDDSTDGFHDICG-PNKELD----- 287
      ||  | : | : | || |  || : |  || | : ||
Db      872 ----CPGTQKWMDCKCKGCPNAQTDC-----AGGKKFNDFTCSCGCPSGKLDCTGNTKW 922

Qy      288 -EETCQCVCRAGLRPASCGPHKELDRNSQCVCCKNKLFPSCGANREFDENTCQCVCKR- 345
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Qy      346 -----TCPRNQPLNPGKCACECTESPQKCLLKGKKFHH 378
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Qy      379 QTCSCYRRPCTNRQKACEPGFSYSEEVCRCV 409
      |  | | | || : : | : |
Db      1041 DKCVV---ECAN-VKTCEGPQRWCDNQCKCI 1067

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SEQ ID NO:4

S08167

Balbiani ring 3 protein - midge (Chironomus tentans)

C;Species: Chironomus tentans

C;Date: 30-Sep-1991 #sequence_revision 30-Sep-1991 #text_change 21-Jul-2000

C;Accession: S08167

R;Paulsson, G.; Lendahl, U.; Galli, J.; Ericsson, C.; Wieslander, L.

J. Mol. Biol. 211, 331-349, 1990

A;Title: The balbiani ring 3 gene in Chironomus tentans has a diverged repetitive structure split by many introns.

A;Reference number: S08167; MUID:90172404

A;Accession: S08167

A;Status: not compared with conceptual translation

A;Molecule type: DNA

A;Residues: 1-1700 <PAU>

A;Cross-references: GB:X52263; NID:g7057; PIDN:CAA36506.1; PID:g7058

C;Genetics:

A;Gene: BR3

A;Map position: 4

C;Superfamily: unassigned Balbiani ring proteins

Query Match 12.9%; Score 257; DB 2; Length 1700;
Best Local Similarity 22.8%; Pred. No. 1.8e-11;
Matches 89; Conservative 47; Mismatches 145; Indels 110; Gaps 18;

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Qy      10 KMYKCQLRK----GGWQHNREQANLNSRTEETIKFAAAHYNTEILKSIDNEWRKTCMPR 65
      |  ||: |   || ::|::      :||      || | :   |  |
Db      727 KTCKCKCEKEMPTGGCENNKKWC-----DETCDCVCPQKNTCIAPKV---WDAKTCS-- 775

Qy      66 EVCIDVGKEFGVATNTFFKPPCVSVYRCGG-----CCNSEGLQCMNTSTSYLSKTLF 117
      ||              ||: :|      || : ::      :: : :
Db      776 --CI-----CVNPPKCNSPQVLKDTCCCGCQNVKSKCAPQKFI-ENIC 815

Qy     118 EITVPLSQGPKPVTISFANHTSCRCMSKLDV-----YRQVHSIIRSLPATLPQCQA 169
      :  | : | :   || : :      : :|      : |  | |
Db     816 DCACPNKKQCKAPLVWSDEFCDVCVPNSASMKTCLSPKEWNKVTCTCDCNPPK--PDC-- 871

Qy     170 ANKTCPTNYMWNNHICRC---LAQEDFMFSSDAGDDSTDGFHDICG-PNKELD----- 218
      ||   | : | :|  || |   ||   : |  || | : :||
Db     872 ----CPGTQKWMDDKCKCGCPNAQTDC-----AGGKKFNDFTCSCGCPSGKLDCTGNTKW 922

Qy     219 -EETCQCVCVCRAGLRPASCGRPHELDNRNSCQCVCKNKLFPSCGANREFDENTCQCVCKR- 276
      ||| | | |   :|| | : | ||| ||||   : | : | :: :||:||||
Db     923 SAETCTCGC--GDVNRNCGNLKNFNDNLCQCECKNKQEMANCKSPRTWNYDTCKCVCKNA 980

Qy     277 -----TCPRNQPLNPGKCACECTESPQKCLLKGKKFHH 309
      ||| | :   | :|||   : :||| : :
Db     981 DDSDDCVKPQIWLDDQCKCGCPASAQMTCPANKRFIEKSCSCECKSPMPSPPIQGGKKWNE 1040

Qy     310 QTCSCYRRPCTNRQKACEPGFSYSEEVCRVCV 340
      |   | | | ||   : : | :| :
Db    1041 DKCVV---ECAN-VKTCEGPQRWCDNQCKCI 1067

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